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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/567,419	08/21/2006	Juan-Miguel Garro Galvez	ROBCA13.002APC	6922
20995 7590 09/26/2007 KNOBBE MARTENS OLSON & BEAR LLP 2040 MAIN STREET FOURTEENTH FLOOR IRVINE, CA 92614			EXAMINER KATAKAM, SUDHAKAR	
			ART UNIT 1621	PAPER NUMBER
			NOTIFICATION DATE 09/26/2007	DELIVERY MODE ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com  
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**Office Action Summary**

Application No.

10/567,419

Applicant(s)

GALVEZ ET AL.

Examiner

Sudhakar Katakam

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 09 July 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-10,14,15 and 17-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10,14,15 and 17-21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>8/15/07</u> . | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Status of the Application*

1. Receipt of Applicant's Remarks and Arguments filed on 9<sup>th</sup> July 2007 is acknowledged. The previous rejection based on the 112 has been vacated in view of applicants' amendments to the claims and cancellation of claim 16. Claims 18-21 have been added. Applicants' arguments have been considered but are moot in view of the following new ground(s) of rejection.

### *Claim Rejections - 35 USC § 103*

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 1-10, and 14-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Sih et al** (US 6,316,645) in view of **Lee** (US 6,664,405), **Tanino et al** (US 4,499,010) and **Shirai et al** (JP 2000336029 A).

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The instant claims are drawn to a preparation of a composition comprising a mixture of linolenic acids, viz., 9cis,11trans,15cis-octadecatrienoic acid and 9cis,13trans,15cis-octadecatrienoic acid, characterized in that said linolenic acids are present in a ratio of 1:1 w:w and said mixture varying between 30% and 90% by weight relative to the weight of the composition, said process comprising the steps of blending one or a mixture of vegetable oils with various concentrations of linolenic acid or partial glycerides with a base and in the presence of water, and removing the resulting conjugated linolenic acids.

**Sih et al** teach a preparation of a composition of linolenic acids, which comprises 9cis,11trans,15cis-octadecatrienoic acid and 9cis,13trans,15cis-octadecatrienoic acid, and other linolenic acids [see Fig.2]. It also discloses that the crude reaction product comprises these compounds [see examples]. The process also use a base in the preparation [col. 5, lines 1-7].

The difference between the instant claims and the **Sih et al** is that in the instant claims composition the linolenic acids, viz., 9cis,11trans,15cis-octadecatrienoic acid and 9cis,13trans,15cis-octadecatrienoic acid having the ratio of 1:1, whereas **Sih et al** is silent on this ratio. Another difference is that instant claims composition preparation includes the water, whereas **Sih et al** is silent on the use of water in the process.

It is common practice in the art to make the desirable ratio of the known compounds in a composition and these are optimizable parameters, and hence are not patentable.

With regard to the water in the process, **Lee** teaches a method for isolating high-purified unsaturated fatty acids from vegetable oils and process includes a step of adding water and then recovering the unsaturated fatty acids [col. 4, lines 1-34].

Therefore, the examiner finds that it would have been obvious to a person of ordinary skill in the art, at the time of present invention was made, to have modified the reference's teachings by using the known compounds and processes, to make the instant applicants' composition with a reasonable expectation of success.

Some limitations of the dependent claims may not be expressly disclosed in references. However, these limitations appear to be drawn to tweaking the process conditions, such as temperature and range of oils and bases, in the process of preparing conjugated linolenic acids.

Changing such parameters is prima facie obvious because an ordinary artisan would be motivated to optimize the reaction conditions such as temperature and use known methods of preparation. Merely modifying the process conditions such as temperature and concentration is not a patentable modification absent a showing of criticality. In re Aller, 220 F.2d 454, 105, USPQ 233 (CCPA 1955).

Claim 14 is further limited to a method of obtaining a varnish composition, comprising mixing the applicants' linolenic acid composition with a varnish.

**Tanino et al** teach a conductive paint, which comprises of fatty acids, viz., oleic, linoleic acid, and linolenic acid [col. 14, lines 23-39].

The difference between the instant claims and the **Tanino et al** is that instant claims specifically uses the 9cis,11trans,15cis-octadecatrienoic acid and

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9cis,13trans,15cis-octadecatrienoic acids in the varnish, whereas **Tanino et al** generically teaches the use of linolenic acids in the paints.

It would have been obvious to a person of ordinary skill in the art, at the time of present invention was made, to have modified the **Tanino et al** teachings, and to make the applicant's varnish, with a reasonable expectation of success.

Claims 15, and 17-21 are further limited to a method of inducing apoptosis of mammalian solid neoplastic cancer cells, comprising contacting said cells with a therapeutically effective amount of the composition.

**Shirai et al** teach a breast cancer inhibiting agent contains a conjugated linolenic acids, which comprises of 9,11,13- octadecatrienoic acid, 10,12,14-octadecatrienoic acid, their mixture etc [see abstract, translation of full article is pending].

The difference between the instant claims and the **Shirai et al** is that the reference silent (according to the abstract) on using the cancer cell lines, whereas instant claims are specific to breast cancer cell lines.

It would have been obvious to a person of ordinary skill in the art, at the time of present invention was made, to apply the **Shirai et al** teachings. One would have been motivated to do this because **Shirai et al** teaches "breast cancer inhibiting agent contains a conjugated linolenic acids, which comprises of 9,11,13- octadecatrienoic acid, 10,12,14-octadecatrienoic acid, their mixture etc". Therefore, the instant claimed method is made obvious over the reference.

### ***Double Patenting***

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the

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unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 1-8 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the claims of copending U.S.

Application No.10/523,863.

Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following reasons:

They generically overlap. The applications are drawn to a process for the preparation of a composition comprises conjugated linolenic acids, viz., 9cis,11trans,15cis-octadecatrienoic acid, and 9cis,13trans,15cis-octadecatrienoic acid. The mixture can be purified by liquid chromatography.

The difference between the instant claims and the claims in the copending application is that the instant claims characterized the ratios of the components in the

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mixture, whereas copending application is silent on these ratios (as can be seen from examples). Another difference is that present claims process is carried out in presence of water, whereas copending application is silent on the water in the process.

It would have been prima facie obvious at the time the invention was made to one of ordinary skill in the art to start with the teachings of the cited copending applications to make instant applicants' process and to expect to the components in certain ratios in the composition. The difference, however, does not constitute a patentable distinct, because the claims in the present invention simply fall with in the scope of copending application, since the similar reactants and conditions. Hence the instant claims overlap with the claims of the copending application. Please note that the copending claims say "comprising" and that means the process may include other components in the preparation, such as water.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not been patented yet.

### ***Conclusion***

7. No claim is allowed.


8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sudhakar Katakam whose telephone number is 571-272-9929. The examiner can normally be reached on M-F 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on 571-272-0871. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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